

COMMONWEALTH OF VIRGINIA
Department of Health Professions
6606 West Broad Street, 4th Floor
Richmond, Virginia 23230

DATE: _____
TIME: _____
MILEAGE: _____
INSPECTION HOURS: _____

COMPRESSED MEDICAL GASES INSPECTION REPORT

Facility Name: _____ Permit No.: _____ Exp. Date _____
Address: _____
Owner: _____ Lic. No.: _____ Exp. Date _____
Person in Charge: _____ Phone No: _____ Hrs. of Oper. _____

	<u>YES</u>	<u>NO</u>	<u>DOCUMENTATION</u>
<u>FACILITY:</u>			
1. Required licenses displayed?	_____	_____	
2. Facility is of adequate size to facilitate proper operation?	_____	_____	
3. Storage area provides adequate lighting, ventilation, temperature and sanitation?	_____	_____	

EQUIPMENT

4. Suitably located to facilitate filling process, yes or no? If no, document.	_____	_____	
5. CMG manifolds dedicated to a single gas (e.g. oxygen), yes or no? If no, document.	_____	_____	
6. Manifold equipped with fill connection that corresponds to container value connection, yes or no? If no, document.	_____	_____	

Testing and Approval or Rejection of Components

7. Each lot of components withheld from use until lot has been tested, yes or no? If no, document.	_____	_____	
8. In lieu of test, does manufacturer accept report of analysis from supplier, yes or no? If no, document.	_____	_____	

Testing of Drug Product Containers and Closures

9. Test of CMG container/closures include the following each time container/closure is refilled:			
a. Odor test to detect foreign odors, yes or no? If no, document.	_____	_____	
b. Visual inspection of values and container for dents, burns, oil or grease, yes or no? If no, document.	_____	_____	

	<u>YES</u>	<u>NO</u>	<u>DOCUMENTATION</u>
c. Visual checks of container coating for evidence of exposure to heat or fire, yes or no? If no, document	_____	_____	
d. Dead ring test performed on steal container, yes or no? If no, document.	_____	_____	
e. Hydrostatic test conducted at required intervals and date of last test marked on containers, yes or no? If no, document.	_____	_____	
f. Container of proper color corresponding to color code system, yes or no? If no, document?	_____	_____	
g. Container contain proper value type for CMG involved, yes or no? If no, document.	_____	_____	
h. Vacuum pulled on each cylinder prior to filling with CMG to remove foreign gas and residue, yes or no? If no, document.	_____	_____	

Labeling Issuance and Packing and Label Operations

10. Written procedures maintained to assure that current labels, labeling and packaging materials are used, yes or no? If no, document.	_____	_____	
11. Procedure include the following:	_____	_____	
a. Number of labels issued, yes or no? If no, document.	_____	_____	
b. Number of containers actually re-labeled, yes or no? If no, document.	_____	_____	
c. Number of labels destroyed and/or returned to inventory, yes or no? If no, document.	_____	_____	

Testing and Release for Distribution

12. Written procedures for teasing and sampling finish products include method of sampling, number of units per batch to be tested, yes or no? If no, document.	_____	_____	
13. Testing performed on CMG's before release in certain type of filling operation as follows:			
a. If cylinder filled from a multi cylinder manifold, is one cylinder tested from each manifold filling for identity and strength each time cylinder, are changed on manifold, yes or no? If no, document.	_____	_____	

- b. If cylinder filled one at a time by individual filling operations, is one cylinder for each uninterrupted filling cycle tested for identity and strength, yes or no? If no, document. _____
- c. If liquefied gas placed in home units at plant, is each home unit tested for identity and strength, yes or no? If no, document. _____
14. Firms dispensing liquid oxygen from vehicle mounted vessels conduct tests for identity and strength is follows:
- a. If both suppliers perform identity and strength test, is test witnessed by HRC and documentation of test maintained by HRC, yes or no? If no, document. _____
- b. If identity and strength test is not witnessed by HRC, does HRC perform identity and strength test on each lot, yes or no? If no, document. _____
- c. If HRC maintains a stationary holding tank, does HRC perform a test for identity and strength after each delivery before mounted vessels is filled, yes or no? If no, document. _____

Batch Production and Control Records

15. An accurate reproduction of appropriate master production or central record maintained to include:
- a. Date, yes or no? If no, document. _____
- b. Signature, yes or no? If no, document. _____
- c. Documentation that each step in manufacturing process was completed, yes or no? If no, document. _____

General Remarks:

Action Taken:

- (1) _____ New Inspection
(2) _____ Routine Inspection
(3) _____ Reinspection
(4) _____ Drug Destruction
(5) _____ Drug Audit
(6) _____ Other _____

(Specify)

Acknowledgement:

This wholesaler has been inspected by an inspector of the Department of Health Regulatory Boards. The results of the inspection have been noted. I acknowledge that the noted conditions that have been deemed by the inspector as not being in compliance have been explained to me and that I have received a copy of this inspection report.

Inspector (Dept. of Health Professions)

Person in Charge

Date

Time of Exit

Title of Authorized Individual